

Food and Drug Administration College Park, MD 20740

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APR 1 6 2004

Mr. Emil Chiaberi Chief Executive Officer Spirit Sciences USA, Inc. 6733 S. Sepulveda Boulevard Suite 108 Los Angeles, California 90045

Dear Mr. Chiaberi:

This is in response to your letter of February 23, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Spirit Sciences USA, Inc. is making the following claims, among others, for the product RU-21[®]:

"Acetaldehyde is a toxic byproduct of alcohol metabolism that has been linked to both, most alcohol related injuries and the addictive process "Prevents hangovers"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases (i.e., chronic diseases associated with overuse of alcohol, alcohol addiction, and the consequences of alcohol poisoning/overdose (i.e., hangover)). These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Page 2 - Mr. Emil Chiaberi

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Spirit Sciences USA, Inc. Emil Chiaberi Chief Executive Officer 6733 S. Sepulveda Blvd., Suite 108 Los Angeles, CA 90045 (310) 568-1030 Fax: 861-5612

MAR 0 9 2004

February 23, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW. Washington, DC 20204

Re: Dietary Supplement Statement of Support Notification

To Whom It May Concern:

Spirit Sciences USA, Inc. of 6733 S. Sepulveda Blvd., Suite 108, Los Angeles, CA 90045, who is the distributor of the following dietary supplement product, intends to make the following statements of support for RU-21 Dietary Supplement: "Naturally supports the body's ability to metabolize alcohol"; "Supports morning energy"; "Supports healthy skin"; "Promotes healthy DNA", "Supports Reproductive Health".

These claims are being made for succinic acid, fumaric acid, L-glutamine, glucose and vitamin C, which are contained in RU-21 Dietary Supplement. This submission in being made in compliance with 21 CFR §101.93.

The undersigned is an authorized representative of the Spirit Sciences USA, Inc. and certifies that the information contained in this notice is complete and accurate, and that Spirit Sciences USA, Inc. has substantiation that the above statements are truthful and not misleading.

Edish!

Emil Chiaberi

Chief Executive Officer

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SUPER VALLUB 10 Servings Inside!

SAFE AND EFFECTIVE 199%

> SAFE AND EFFECTIVE **100**%

Natural oxidation processes may cause some tablets to acquire a stightly brown color. Change in color DUES NOT affect the praduct's potency.

ABOUT ACETALDENYDE

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Distributed by Spirit Sciences USA, Inc.. 9454 Wilshira Bivd., Suite 666, Beverly Hills, CA 90212

U.S. Patent Pending

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CLINICALLY TESTED

REGULATES ALCOHOL METABOLISM

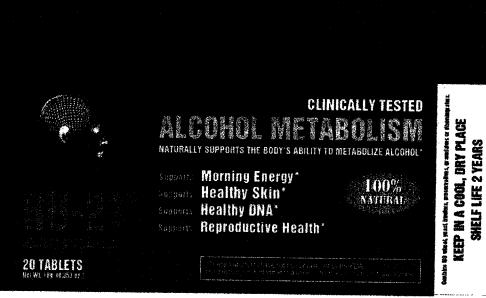
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20 TABLETS

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New Claims



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> ONEVIAM ANUAR GNA Meliomolia Thora glem

> > SUPER VALUE

MAINTAIN VOLUE HERALETS

Supplement Facts Serving Size 2 tablets

Amount Per Serving % Daily		Dany Verus
Vilamin Ç	50 mg	637
Succinic Acid	200 mg	
Fumaric Acid	75 mg	
L-Glutaming	200 mg	

Other rigredients Glacose (Dexfrose)

SUGGESTED USE: 198 198 198 1981 with the section of the first and order

Natural exidation processes may cause some tablets to acquire a slightly brown color. Change in color DOES NOT affect the product's potency.

ABOUT ACETALDENVOE

Acetaldehyde is a toxic byproduct of alcohol metabolism that has been linked to both, most alcohol related injuries and mo addictive process itself

Distributed by Spirit Sciences USA, Inc. 9454 Wilshire Blvd, Sulle 800 **Beverly Hills, CA 90212** URL: WWW.RU21.COM

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